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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/087,871	06/02/98	WAGNER	G 0708-4038

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HM12/0313

EXAMINER

GABEL, G

ART UNIT

PAPER NUMBER

1641

12

DATE MAILED: 03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/087,871

Applicant(s)

WAGNER, GERALD

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-21 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
  2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
  3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

14) ☐ Notice of References Cited (PTO-892)

15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

18) ☐ Notice of Informal Patent Application (PTO-152)

19) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 2/2/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/087,871 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Amendment Entry***

2. Applicant's amendment and response filed 5/10/00 in Paper No. 8 is acknowledged and has been entered. Claims 1 and 7-12 have been amended. Claims 1-12 are pending and under examination.

### ***Restriction Requirement***

3. Applicant's traversal of the restriction requirement in Paper No. 6 is acknowledged. The traversal is on the grounds that the inventions are obvious over each other within the meaning of 35 USC § 103.

Applicant's argument is not found persuasive because restriction requirements are set forth for reasons of patentable distinction between each independent invention so as to warrant separate classification and search. The record set forth in the previous restriction requirement clearly indicated that the delineated inventions are in fact

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patentably distinct each from the other or independent from the other. The requirement is still deemed proper and is therefore made FINAL for reasons of record.

### ***Drawings***

4. The application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 remains vague and indefinite in reciting "wherein said processor supports the diagnosis of the pathology" because it is unclear what is encompassed by the term "supports". For example, does applicant intend to encompass "providing diagnostic information on the pathology...".

Claim 7 remains indefinite and unclear in reciting "additional stored information" because the claim includes elements not actually disclosed (those encompassed by "additional"), thereby rendering the scope of the claim unascertainable. See MPEP §

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2173.05(d). As claimed, applicant appears to intend to additionally include information other than "results from the measurements executed according to the reflex algorithm and ...", "stored information" and "medical/family history....", etc. Applicant's argument in page 7 of Paper No. 8 is not persuasive because it is not commensurate in scope with the claimed invention.

Claims 8, remains indefinite and incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Claim 8 fails to specify what element in the hematology analyzer communicates with the processor so as to enable it to respond and execute specific commands. See claim 2.

Regarding claim 9, the term "including" renders the claim indefinite because it is unclear what other limitations following the term are included in the claimed invention and how the elements within the claim interrelate. See MPEP § 2173.05(d).

Redundancy in element recitation further renders the claim confusing. The following language is suggested but not required to assist Applicant in clarifying the claim. In line 2 after pathology, --the biological marker measurements including an immunoassay measurement and a clinical chemistry assay measurement, the measurement steps comprising measuring a concentration level...--. Same analogous comments apply to claim 10.

Claim 11 as amended is vague and indefinite in reciting "provides a suggested indication" because it is unclear as to what element the processor intends to selectively

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provide. For example, does applicant intend to encompass providing --diagnostic information indicative of a pathology--.

Claim 12, as amended, is vague, confusing, and recites inconsistent language in reciting "include a first processor and a second processor...". For example, does Applicant intend for the first and second processors to be --local-- processors that communicate with the "said processor" in claim 10.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph for reason of record. To reiterate, the specification, while being enabling for acute myocardial infarction biochemical markers, does not reasonably provide enablement for other biochemical markers, such as thyroid profile markers and hepatitis profile markers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

7. In light of applicant's argument, the rejection to claim 9 under 35 U.S.C. 112, first paragraph is, hereby, withdrawn.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lillig et al. (US 4,965,049) in view of Groth et al. (US 5,690,103) and in further view of Furlong et al. (Clinical Chemistry, 1990) for reasons of record.

***Response to Arguments***

9. Applicant's arguments filed 5/10/00 have been fully considered but they are not persuasive.

10. a) Applicant argues that Lillig, Groth, and Furlong individually or in combination do not teach or suggest, inter alia, a system that includes an immunoassay analyzer and a clinical chemistry assay analyzer that are controlled according to "reflex algorithm" which refers to an algorithm in which selection of subsequent test is based on previous tests without human subjective decision-making involvement in selecting such tests.

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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that Lillig, Groth, and Furlong in combination do not teach or suggest what is taught by the instant invention, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Lillig discloses a system combining analyzers, each adapted for independent operation and each possessing different operational characteristics for different applications wherein each modular analyzer is adapted to operate as a portion of a system of modular analyzers (see column 2, lines and 8-26 and Figure 3). The system includes a first analyzer and a second analyzer each including a sample carousel, analyzing means, and automated probe means for transferring samples from the sampling carousels to the analyzing means. Electronic and electrical interfaces form public and/or private networks between analyzers so as to form the system and operational information and instructions are coded into the analyzers through a disk drive (see column 6, lines 51-65). Groth is incorporated herein for his teaching of computer based neural networks

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design incorporated into analyzers where measured patient results (analyte concentrations, enzymatic activities, etc.) are compared and referenced with biochemical marker standards from preclassified example cases to provide an indication of a pathology. Groth discloses that the computer system is designed to perform specific computational tasks to support a decision tree that provides a feedback mechanism of what subsequent measurements are to be performed based on the most recent measure; the end product of which provides a diagnostic indication of a pathology (see column 5 and column 8). Likewise, Furlong has been incorporated herein for his teaching of computerized neural network analysis specifically of cardiac data for use as clinical decision-making aid wherein computer hardware and software emulate biological nervous systems formed by interconnected artificial neurons (see page 135, column 1, first full paragraph). Such artificial intelligence programs use algorithmic process for decision making wherein clinicians knowledge has been distilled in a hierarchy of facts or rules wherein the matrix of synaptic weighting factors are calculated using back propagation, supervised learning algorithm (see page 134, column 2, last paragraph). One of ordinary skill in the art at the time of the invention would have been motivated to increase automated diagnostic versatility into the high-throughput capacity of modular designed analyzer systems taught by Lillig by incorporating decision support systems such as the computerized neural network as taught by Groth and Furlong because in assessing proper emergency management of crisis patients, especially those suspected of myocardial infarction, specific and

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accurate results obtained at a limited amount of time coupled with anticipatory diagnostic procedure, are critical to the treatment and survival of patients.

b) Applicant argues that Lillig fails to describe immunoassay tests, only clinical chemistry tests.

In response to applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which applicant relies (i.e., immunological tests) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Alternatively, immunological analyzers are well-known in the art which represent an obvious "modular" equivalent variation of what is generally referred to as clinical chemistry analyzers. Incorporation of specific "immunological" reagents and parameter conditions into such analyzers for specific immunological reactions in a diagnostic system is conventional and generally within ordinary skill.

c) Applicant further contends that neural network taught by both Groth and Furlong is a stark contrast to reflex algorithm as claimed by Applicant because neural network classifies according to predetermined set of biochemical markers which are all input into the neural network.

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Contrary to Applicant's argument, the "reflex algorithm" as claimed in the instant invention is an inherent property of neural network design disclosed by prior art because neural networks provide for feedback mechanism which further provides for a decision and suggestion to perform other activity or to activate another network structure which Groth refers to as a "feedback connection from conclusive diagnostic unit" (see column 16, lines 42-67) so that further testing, if desired, can be activated into preprogrammed analytical computer software to further analyze a blood sample. Incorporation of such a capability is an obvious design choice to one of ordinary skill, taking advantage of neural network capacity to provide feedback mechanism to further activate "function" into another neural structure, in this case, to pursue further subsequent testing by the analyzer.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*J. Gabel* 3/10/01

Gailene R. Gabel  
Patent Examiner  
Art Unit 1641

*Long V. Le*

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03/12/01